

**ACETAMINOPHEN, CHLORPHENIRAMINE MALEATE, PHENYLEPHRINE  
HYDROCHLORIDE- acetaminophen, chlorpheniramine maleate, and phenylephrine  
hydrochloride tablet, coated  
AAA Pharmaceutical, Inc.**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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**RES - 1128 - 2019-1012**

***Drug Facts***

<b><i>Active ingredients (in each caplet)</i></b>	<b><i>Purpose</i></b>
Acetaminophen 325 mg	Pain reliever
Chlorpheniramine maleate 2 mg	Antihistamine
Phenylephrine HCl 5 mg	Nasal decongestant

**Uses**

- temporarily relieves these symptoms of hay fever or other upper respiratory allergies:
  - headache
  - sinus congestion and pressure
  - nasal congestion
  - runny nose and sneezing
  - minor aches and pains
- temporarily relieves these additional symptoms of hay fever:
  - itching of the nose or throat
  - itchy, watery eyes
- helps clear nasal passages
- helps decongest sinus openings and passages

**Warnings**

**Liver warning**

This product contains acetaminophen. Severe liver damage may occur if you take

- more than 12 caplets in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

**Do not use**

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

**Ask a doctor before use if you have**

- liver disease

- heart disease
- high blood pressure
- thyroid disease
- diabetes
- glaucoma
- trouble urinating due to an enlarged prostate gland
- a breathing problem such as emphysema or chronic bronchitis

**Ask a doctor or pharmacist before use if you are**

- taking sedatives or tranquilizers
- taking the blood thinning drug warfarin

**When using this product**

- **do not exceed recommended dosage**
- excitability may occur, especially in children
- drowsiness may occur
- alcohol, sedatives, and tranquilizers may increase drowsiness
- avoid alcoholic drinks
- be careful when driving a motor vehicle or operating machinery

**Stop use and ask a doctor if**

- nervousness, dizziness, or sleeplessness occur
- pain or nasal congestion gets worse or lasts more than 7 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur

These could be signs of a serious condition.

**If pregnant or breast-feeding,** ask a health professional before use.

**Keep out of reach of children.**

**Overdose warning**

Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

**Directions**

- do not take more than directed (see overdose warning)

adults and children 12 years and over	<ul style="list-style-type: none"> <li>• take 2 caplets every 4 hours</li> <li>• swallow whole - do not crush, chew, or dissolve</li> <li>• do not take more than 12 caplets in 24 hours</li> </ul>
children under 12 years	<ul style="list-style-type: none"> <li>• do not use this adult product in children under 12 years of age; this will provide more than the recommended dose (overdose) and may cause liver damage</li> </ul>

**Other information**

- store between 20°-25°C (68°-77°F) in a dry place
- retain carton for complete product information

**Inactive ingredients**

acesulfame potassium, colloidal silicon dioxide, croscarmellose sodium, flavor, hypromellose, iron oxide ochre, lactose anhydrous, magnesium stearate, povidone, pregelatinized starch, propylene glycol, stearic acid, titanium dioxide

**Distributed by:**

AAA Pharmaceutical, Inc.  
681 Main Street  
Lumberton, NJ 08048

**PRINCIPAL DISPLAY PANEL - 24 Caplet Blister Pack Carton**

NDC 57344-128-02

***RESTORE u***

†COMPARE TO THE ACTIVE  
INGREDIENTS IN TYLENOL®  
ALLERGY MULTI-SYMPTOM

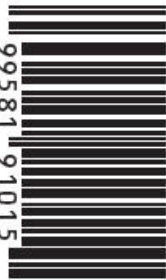
***Allergy******MULTI-SYMPTOM***

Pain Reliever, Nasal Decongestant, Antihistamine

- Headache - **Acetaminophen**
- Sinus Pressure
- Nasal Congestion  
Phenylephrine HCl
- Runny Nose/Sneezing
- Itchy, Watery Eyes  
Chlorpheniramine Maleate

***COOL TASTE******MAY CAUSE DROWSINESS*****24 CAPLETS**

0 99581 91015 0



# RESTORE<sup>U</sup>

# Allergy

## MULTI-SYMPTOM

NDC 57344-128-02  
 +COMPARE TO THE ACTIVE  
 INGREDIENTS IN TYLENOL®  
 ALLERGY MULTI-SYMPTOM

distributed by:  
 Pharmaceutical, Inc.  
 Main Street  
 Berton, NJ 08048

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<b>Drug Facts</b> <b>Active ingredients</b> Acetaminophen 325 mg..... Pain reliever Chlorpheniramine maleate 2 mg..... Antihistamine Pseudoephedrine HCl 5 mg..... Nasal decongestant	
<b>Purpose</b> Temporarily relieves these symptoms of hay fever or other upper respiratory allergies: ■ runny nose and sneezing ■ nasal congestion ■ headache ■ sinus congestion and pressure ■ fever or other upper respiratory allergies ■ temporarily relieves these symptoms of hay fever or other upper respiratory allergies: ■ runny nose and sneezing ■ nasal congestion ■ headache ■ sinus congestion and pressure	<b>Uses</b> Temporarily relieves these symptoms of hay fever or other upper respiratory allergies: ■ runny nose and sneezing ■ nasal congestion ■ headache ■ sinus congestion and pressure ■ fever or other upper respiratory allergies ■ temporarily relieves these symptoms of hay fever or other upper respiratory allergies: ■ runny nose and sneezing ■ nasal congestion ■ headache ■ sinus congestion and pressure

<b>Drug Facts (continued)</b> ■ temporarily relieves these additional symptoms: ■ itching of the nose or throat ■ itchy, watery eyes ■ helps clear nasal passages ■ helps decongest sinus openings and passages <b>Warnings</b> Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take more than 12 caplets in 24 hours, which is the maximum daily amount. ■ With other drugs containing acetaminophen 3 or more alcoholic drinks every day while using this product. Do not use ■ with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist. ■ If you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychotic, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug, if you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.	
<b>Drug Facts (continued)</b> <b>Stop use and ask a doctor if</b> ■ new symptoms occur ■ fever gets worse or lasts more than 3 days ■ redness or swelling is present ■ more than 7 days ■ path or nasal congestion gets worse or lasts more than 7 days ■ nervousness, dizziness, or sleeplessness occur ■ Stop use and ask a doctor if ■ new symptoms occur ■ fever gets worse or lasts more than 3 days ■ redness or swelling is present ■ more than 7 days ■ path or nasal congestion gets worse or lasts more than 7 days ■ nervousness, dizziness, or sleeplessness occur <b>Keep out of reach of children.</b> Overdose warning: Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact Poison Control Center right away (1-800-222-1222). Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.	
<b>Directions</b> ■ do not take more than directed (see overdose warning) adults and children 12 years and over ■ take 2 caplets every 4 hours ■ swallow whole - do not crush, chew, or dissolve ■ do not take more than 12 caplets in 24 hours children under 12 years ■ do not use this adult product in children under 12 years of age; this will provide more than the recommended dose (overdose) and may cause liver damage	

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## ACETAMINOPHEN, CHLORPHENIRAMINE MALEATE, PHENYLEPHRINE HYDROCHLORIDE

acetaminophen, chlorpheniramine maleate, and phenylephrine hydrochloride tablet, coated

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57344-128
Route of Administration	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
CHLORPHENIRAMINE MALEATE (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)	CHLORPHENIRAMINE MALEATE	2 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

### Inactive Ingredients

Ingredient Name	Strength
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)				
STARCH, CORN (UNII: O8232NY3SJ)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
STEARIC ACID (UNII: 4ELV7Z65AP)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
Product Characteristics				
Color	white (Off-White)		Score	no score
Shape	OVAL		Size	17mm
Flavor	MINT		Imprint Code	AAA;1117
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57344-128-02	2 in 1 CARTON	08/02/2012	
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
OTC monograph final	part341		08/02/2012	

**Labeler** - AAA Pharmaceutical, Inc. (181192162)

Revised: 10/2019

AAA Pharmaceutical, Inc.